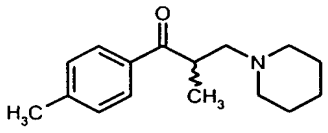
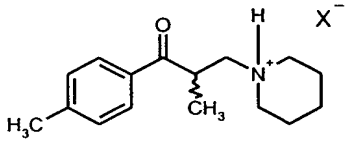
Amended patent claims:

1. Method for manufacturing pharmaceutically acceptable acid addition salts of 2,4'-dimethyl-3-piperidinopropiophenone (tolperisone), of formula (A)



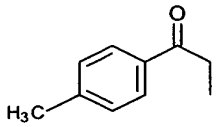
(A)

said acid addition salts having a formula (B)

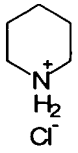


(B)

whereby 4-methylpropiophenone of the formula



is reacted with piperidine hydrochloride of the formula



and 1,2-dioxolane of the formula

in presence of an acid as catalyst, characterized by the fact that tolperisone is separated as an acid addition salt in accordance with the general formula (B) after cooling the reaction mixture by addition of ethyl acetate and tert- butylmethylether to cause precipitation.

2. Method according to claim 1, characterized by the fact that the reaction is carried out in the presence of catalytic quantities of an acid, in particular aqueous hydrochloric acid.

3. Method according to claims 1 or 2, characterized by the fact that the reaction is carried out in a solvent.

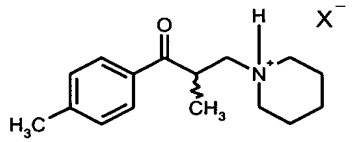
4. Method according to claim 3, characterized by the fact that the reaction is preferably accomplished in 1,2-dioxolane as a solvent in a concentration range from 1 to 6 preferably 3.6 mol/lit.

5. Method according to claims 1 to 4, characterized by the fact that the resulting tolperisone with the inorganic acid, such as hydrochloric acid is converted, into the addition salt.

Method for Producing Salts of Tolperisone

Abstract

The invention relates to a method for producing an acid addition salt of 2,4'-dimethyl-3-piperidino-propiophenone (tolperisone) with a pharmaceutically acceptable acid, of the formula (I).



According to the invention, 4-methylpropiophenone is reacted with piperidine hydrochloride and 1,2-dioxolane in the presence of an acid serving as a catalyst, and the tolperisone obtained in the form of an acid addition salt is separated by filtering after the reaction mixture has cooled down.